UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

UNITED STATES OF AMERICA, et al., Plaintiff, *ex rel.* JAMIE SIEGEL M.D., Plaintiff-Relator, v. NOVO NORDISK, INC., Defendant.	CASE NO. C23-5459 BHS ORDER

THIS MATTER is before the Court on defendant Novo Nordisk, Inc. (NNI)'s motion to dismiss counts 1, 2, and 7 of *qui tam* plaintiff/Relator Jamie Siegel's operative third consolidated complaint. Dkt. 275.

I. BACKGROUND

NNI is a global healthcare company. Among other products, NNI manufactures and sells a hemophilia drug called NovoSeven. Hemophilia is a rare genetic bleeding

disorder that prevents normal blood clotting, due to a lack of proteins known as "clotting factors." It affects about 20,000 people in the United States. Most of these people can be treated with replacement clotting factors, but a subset of hemophilia sufferers (about 1,500 nationwide) develops an antibody, or inhibitor, to their deficient or missing clotting factors. As a result, these patients require a "bypass agent" to allow clotting and stop bleeding. NovoSeven is one of two[1] bypass agent drugs approved by the FDA to treat acute bleeding in hemophilia patients. The other is a drug known as FEIBA, manufactured by Baxter International, Inc.

Plaintiff-Relator Jamie Siegel is a medical doctor employed by NNI between 2008 and 2009 as its Director of Hematology in Clinical Development Medical and Regulatory Affairs. She contends that NovoSeven is approved only to treat acute bleeds, administered in doses of "90 µg/kg"[2] every two hours until the bleeding stops. She alleges that NovoSeven is not FDA-approved for "prophylaxis"—regular treatment with a bypass agent to prevent bleeding in the first place. Siegel asserts that FEIBA is approved both to treat acute bleeds and for prophylaxis use. Dkt. 270 at 6.

NovoSeven is staggeringly expensive. Siegel contends that a hemophilia patient using it for acute bleeds would use, on average, $670,000 worth of NovoSeven per year. Dkt. 281 at 19 (citing her Third Consolidated Complaint, Dkt. 270, ¶ 243). She contends

[1] Siegel asserts that the Food and Drug Administration (FDA) approved the use of a third medication, Hemlibra, in 2017, after the events described in her initial 2015 complaint. Dkt. 270 at 28 n.21.

[2] A µg is a microgram (1 millionth of a kilogram).

that NNI instead sold an average of $4 million of NovoSeven per patient, per year, during the time frame of her complaint. Dkt. 270, ¶¶ 14, 104. She contends that that Medicare paid more than a billion dollars for NovoSeven for about 200 patients between 2008 and 2017. *Id*. at 76.

Siegel's core allegation is that, faced with this small pool of potential patients and its only competitor's broader and thus superior FDA approvals, NNI engaged in various illegal schemes to persuade patients to seek, and physicians to prescribe, NovoSeven, rather than FEIBA. She describes this effort as a "Battle of the Brands." *Id*. at 3. She asserts that NNI's efforts were successful and led to the submission of "false claims" to the United States (and individual states) for payment, under Medicaid, Medicare, and similar programs.

In February 2015, Siegel brought this False Claims Act (FCA) case in the Western District of Oklahoma, on behalf of herself, the United States, 29 states (including Washington), Washington D.C., and Chicago. She alleges the illegal schemes involved promoting NovoSeven for "off-label" uses—prophylaxis and doses exceeding the FDA-approved amount—and providing "kickbacks" to physicians and patients to prescribe and use NovoSeven. Dkt. 1. Siegel alleges that NNI's scheme was national in scope, and that it resulted in the submission and payment of false claims by the federal government and 29 states.

In January 2020,[3] the State of Washington intervened in the case. It "converted" the case to an enforcement action by Washington's Attorney General, as to the claims that NNI's kickback and off-label marketing scheme resulted in the submission of false claims to the Washington Medicaid program, violating Washington's Medicaid Fraud False Claims Act, chapter 74.66 RCW, and Washington's Fraudulent Practices Act, RCW 74.09.210. Dkt. 85. With Relator Siegel, Washington filed a "consolidated second amended complaint" in May 2020. Dkt. 122. The United States has not intervened but has reserved its right to notice and to intervene later. Dkts. 98, 104. No other state has intervened.

Siegel and Washington's consolidated second amended complaint asserted thirty-five "counts" or claims. It included as counts 1 and 2 the two federal FCA claims described above, and parallel state law claims, including a claim under Delaware law, count 7, and two Washington state law claims, counts 31 and 32. Dkt. 122. NNI moved to dismiss the case in its entirety in March 2020, arguing that Siegel had failed to satisfy Federal Rule of Civil Procedure 9(b)'s heightened pleading standard for fraud claims and had failed to state a plausible claim. Dkt. 124.

The Western District of Oklahoma's Judge Patrick R. Wyrick dismissed counts 3–30 and 33–35 without prejudice, as insufficiently pled. Dkt. 174. He concluded that Siegel's allegations about false claims submitted for one Washington patient ("Patient A") plausibly stated federal FCA claims (counts 1 and 2), a Washington Medicare False

[3] The case was sealed between 2015 and May 2020. Dkt. 123.

Claims Act (WFCA) claim (count 31), and a Washington Fraudulent Practices Act (WFPA) claim (count 32). *Id*. at 19–20. He explained that, unlike her allegations regarding other patients in other states, Siegel had plausibly and specifically pled that NNI "plied [Patient A] and his guardian with money and in-kind donations including tutoring lessons, travel and meal expenses, computer programming, a computer and a wheelchair" to induce him to use the drug NovoSeven." Dkt. 174 at 12. He denied NNI's motion to dismiss as to those four claims. Dkt. 174 at 30–31. But he granted it as to Siegel's remaining state law claims, though he acknowledged that Siegel had alleged a national illegal marketing scheme in "great detail":

> But the Court concludes that, having alleged only one representative example of possible false claims submitted to the government between 2009 and 2013 (namely, Patient A in Washington), Plaintiffs have not "provide[d] an adequate basis for a reasonable inference that false claims were submitted as part of that scheme" in twenty-eight other states, plus the District of Columbia and the City of Chicago, "from at least 2001 to the present." To be sure, Plaintiffs need not allege the "where" of "every single submission of a false claim" to sufficiently allege nationwide fraud. *But they must provide more than a single representative example of alleged fraud in one state*.

Dkt. 174 at 21 (emphasis added).

Based on Judge Wyrick's Order, NNI moved for a protective order limiting discovery to false claims in Washington. Dkt. 189. Judge Wyrick granted in part and denied in part NNI's motion. He reiterated that he dismissed most of Siegel's claims because she had provided only one representative example of an alleged false claim, in only one state—Washington:

> Though Plaintiffs may have alleged with particularity a nationwide scheme to violate the Food, Drug, and Cosmetic Act and the Anti-Kickback Statute,

> as this Court has already held, Plaintiffs were required to show "an adequate basis for a reasonable inference that *false claims* were submitted as part of that scheme" in twenty-eight other states, plus the District of Columbia and City of Chicago (as alleged in the Second Consolidated Complaint). One representative example of false claims submitted for one patient in one state did not provide an adequate basis for that nationwide inference. This was not just fatal to Plaintiffs' non-federal claims outside the State of Washington: "Because the Court [found] that the Second Consolidated Complaint fail[ed] to satisfy Rule 9(b)'s requirements with respect to alleged false claims submitted outside the State of Washington," **the scope of the remaining four counts, including the two counts brought under the FCA, is limited to alleged false claims submitted for patients in that state**.

Dkt. 200 at 4–5 (footnotes omitted) (bolded emphasis added).

In April 2023, after Washington intervened and all of Relator Siegel's non-Washington claims were dismissed, the plaintiffs sought, and the Oklahoma Court granted, a change of venue to the Western District of Washington. Dkts. 203, 210. Siegel then asked this Court for leave to amend her complaint again, to allege with precision specific claims and underlying facts showing that NNI's nationwide unlawful marketing scheme caused claims for NovoSeven to be presented to Medicare systems for 44 states, and to allege specific claims and facts showing that NNI's scheme caused the submission of false claims to the state of Delaware. Dkt. 248 at 2. NNI opposed amendment, arguing that Siegel was attempting to re-litigate claims that had already been dismissed (without prejudice). This Court permitted the amendment, and Siegel filed her third consolidated complaint. Dkts. 269, 270.

Siegel alleges NNI engaged in a sophisticated, national, and illegal scheme to increase its sales of NovoSeven. She alleges that NNI paid kickbacks to physicians and patients for prescribing and requesting NovoSeven for off-label, medically unnecessary

uses, including for prophylaxis and at higher than the FDA-approved doses. She details NNI's internal marketing strategies, its efforts to have favorable articles published in medical journals, and its presentations at Continuing Medical Education (CME) seminars, all aimed at increasing off-label sales.

She asserts that these efforts were wildly successful, and that the illegal scheme resulted in millions or even billions of dollars in false claims. Siegel alleges that the scheme and its effects were national in scope, and she seeks to re-plead and rehabilitate both her national FCA claims (counts 1 and 2) and her Delaware False Claims and Reporting Act claim (count 7).

Siegel attempts to bolster the claims Judge Wyrick found lacking in three ways: First, she details her own experiences while she was an NNI employee in 2008 and 2009, including NNI's efforts to expand its NovoSeven market share by promoting off-label uses, including inducements to physicians and patients, for NovoSeven. Second, Siegel incorporates "Medicare counts," purporting to demonstrate the total number of claims or payment for NovoSeven presented to Medicare in 44 states and the District of Columbia over time.

Siegel's third new set of allegations relate to NNI's relationship with pharmacy Accredo in Delaware. Siegel incorporates NNIs contract with Accredo, which provided Accredo discounted pricing for NovoSeven in exchange for providing patients information about "SevenSECURE"—an NNI patient support program that Siegel alleges paid kickbacks and incentives to patients for using NovoSeven. Dkt. 270 at 9–10, 35–37. She alleges that Accredo submitted $62 million in claims for NovoSeven to Delaware

Medicaid, and that amount was paid on behalf of "Patient C" in Delaware. She asserts that at least some of those claims were false.

Siegel's third consolidated complaint also makes additional allegations about NNI's efforts to promote the off-label use of NovoSeven at the Indiana Hemophilia and Thrombosis Center, Inc. (Indiana HTC). It does so not to resurrect her Indiana claims but to support her national FCA claims. She alleges that NNI paid kickbacks to "Key Opinion Leaders (KOLs)," including Dr. Amy Shapiro, the Director of the Indiana HTC, to persuade her to promote off-label uses of NovoSeven. She alleges that Shapiro authored six articles about off-label, prophylaxis and high dose uses of NovoSeven. Dkt. 270 at 57–62.

Judge Wyrick dismissed Siegel's Indiana claim in part because she alleged that Medicare paid $46 million for NovoSeven for six patients at the Indiana HTC, "as indicated," meaning not off-label. Dkt. 174 at 21–22. The new pleading clarifies that the amount of the claims—about $4 million per patient per year—itself indicates that in fact the patients were using NovoSeven in off-label ways. *See* Dkt. 270 at 83; Dkt. 281 at 14.

NNI moves to dismiss Siegel's 31 U.S.C. § 3729(a)(1)(A) and (B) FCA claims (counts 1 and 2) to the extent she seeks to revive those claims to assert national claims based on false claims submitted for patients outside Washington. It argues that Judge Wyrick already dismissed her nationwide FCA claims and left standing only her FCA claims based on false claims submitted on behalf of Patient A in Washington. Dkt. 276 at 12. NNI argues that Siegel's new allegations may bolster her contention there was a fraudulent scheme (allegations that Judge Wyrick already ruled were plausible) but that

her new pleading still fails to plausibly allege the required *link* between the schemes she describes, and any false claims submitted for any patient outside Washington. *Id*.

NNI also seeks dismissal of Siegel's "revived" Delaware state law claim (count 7), which alleges that false claims were submitted on behalf of Patient C. *Id*. It argues that Siegel's new allegations do not "close the gaps" identified by Judge Wyrick in dismissing Siegel's Delaware claim. *Id*.

As an initial matter, the parties disagree about the legal effect of Judge Wyrick's prior orders on this Court. NNI asserts that those orders are the law of the case, and that comity requires this Court to refrain from re-visiting issues already decided by a court of equal authority. Dkt. 293 at 2 n.2 (citing *Joyner v. Reno*, 466 F. Supp. 2d 31, 39 (D.D.C. 2006)). Siegel argues both that her amended pleading more than satisfies Judge Wyrick's concerns about counts 1, 2, and 7, and that this Court is not bound by his rulings in any event. She argues that the Court can and should evaluate her claims "from the ground up, unbound by any prior legal determinations." Dkt. 281 at 10 (citing *United States ex rel. Chao v. Medtronic PLC*, No 2:17-cv-01903-ODW (SSx), 2022 WL 541604, at *4 (C.D. Cal. Feb. 23, 2022)).

Even if the Court can revisit issues Judge Wyrick already resolved, it should not and will not. Judge Wyrick's Order is thorough, well-reasoned, and in the Court's view, correct. He dismissed counts 1 and 2 to the extent they alleged a national FCA claim, and Siegel's Delaware state law claim, because she had not sufficiently pled facts supporting the conclusion that the schemes she described led to the submittal of a false claim outside Washington. Dkts. 174, 200.

Siegel acknowledges that her new pleading is an attempt to provide claims data to revive count 7, and to add "granular national Medicare claims data to justify national discovery as to counts 1 and 2, which were not dismissed but were limited in scope to the State of Washington." Dkt. 270 at 2 n.1. NNI's motion argues that this effort failed, against the standards Judge Wyrick properly identified and applied.

This Order evaluates Siegel's revised claims in light of Judge Wyrick's Order, the new pleading, and the excellent briefing on this motion. It does not revisit, revise, or reverse any prior ruling.

II. DISCUSSION

Dismissal under Fed. R. Civ. P. 12(b)(6) may be based on either the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory. *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990). A plaintiff's complaint must allege facts to state a claim for relief that is plausible on its face. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim has "facial plausibility" when the party seeking relief "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. Although the court must accept as true the complaint's well-pled facts, conclusory allegations of law and unwarranted inferences will not defeat an otherwise proper 12(b)(6) motion to dismiss. *Vasquez v. Los Angeles Cnty.*, 487 F.3d 1246, 1249 (9th Cir. 2007); *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001). "A plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual

allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (cleaned up). This requires a plaintiff to plead "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555).

On a 12(b)(6) motion, "a district court should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." *Cook, Perkiss & Liehe v. N. Cal. Collection Serv.*, 911 F.2d 242, 247 (9th Cir. 1990). However, where the facts are not in dispute, and the sole issue is whether there is liability as a matter of substantive law, the court may deny leave to amend. *Albrecht v. Lund*, 845 F.2d 193, 195–96 (9th Cir. 1988).

A. Siegel's re-pled national FCA claims (counts 1 and 2).

Siegel's third consolidated complaint includes additional factual allegations in an effort to revive her national FCA claims. Sigel alleges that NNI engaged in a nationwide scheme to unlawfully market NovoSeven to a vulnerable patient population for unapproved, dangerous uses, violating the FCA and state analogs. Dkt. 270. She argues that NNI did so using an aggressive, multi-pronged business plan designed to maintain its market share, to take market share from FEIBA, and expand the market for NovoSeven by increasing dose size and frequency. Dkt. 270 at 3–4. She alleges that through misrepresentations, off-label promotions, kickbacks, beneficiary inducements, and the submission of non-reimbursable claims, NNI violated two sections of the FCA.

Count One asserts that NNI violated 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting or causing to be presented a false or fraudulent claims for payment or

approval. Dkt. 270 at 87–88. Count Two asserts that NNI violated 31 U.S.C. § 3729(a)(1)(B) by knowingly making, using, or causing to be made or used, false records or statements material to a false or fraudulent claim. Dkt. 270 at 88–89.

The "essential elements" of an FCA claim are:

> (1) A false statement or fraudulent course of conduct,
> (2) made with the scienter,
> (3) that was material, causing
> (4) the government to pay out money or forfeit moneys due.

See Dkt. 281 at 12 (citing *United States ex rel. Campie v. Gilead Scis., Inc*., 862 F.3d 890, 899 (9th Cir. 2017) (quoting *United States ex rel. Hendow v. Univ. of Phx*., 461 F.3d 1166, 1174 (9th Cir. 2006)). An actual false claim is the *sine qua non* of an FCA violation. *U.S. ex rel. Cafasso v. Gen. Dynamics C4 Sys., Inc.,* 637 F.3d 1047, 1055 (9th Cir. 2011) (quoting *United States ex rel. Aflatooni v. Kitsap Physicians Serv.,* 314 F.3d 995, 997 (9th Cir. 2002)).

Rule 9(b)'s heightened pleading standard applies to FCA actions. *United States ex rel. Bly-Magee v. California,* 236 F.3d 1014, 1018 (9th Cir. 2001). Rule 9(b) requires a party alleging fraud to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). To comply with Rule 9(b), allegations of fraud must state the "who, what, when, where, and how" of the misconduct. *Yess v. Ciba–Geigly Corp.,* 317 F.3d 1097, 1106 (9th Cir. 2003). An FCA plaintiff/relator is *not* required to identify representative false claims to support every allegation; rather, in the Ninth Circuit "it is sufficient to allege '**particular' details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted**."

United States ex rel. Ebeid v. Lungwitz, 616 F.3d 993, 998-99 (9th Cir. 2010) (bolded emphasis added). Nevertheless, the allegations "must be specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *Bly-Magee,* 236 F.3d at 1019.

Thus, NNI correctly contends that to state a plausible claim, an FCA plaintiff must specifically plead that the defendant knowingly submitted a materially false claim, which caused the government to pay money. Dkt. 276 at 8 (citing *Integra Med Analytics LLC v. Providence Health & Servs.*, 854 F. App'x 840, 843 (9th Cir. 2021)). NNI's motion to dismiss is based primarily on its argument that, while Siegel's new factual allegations may augment her claim that there was a fraudulent scheme, they do little (and not enough) to establish that a false claim was submitted on behalf of a patient in Delaware, Indiana, or anywhere other than Washington.

The issues are addressed in turn.

1. Siegel's detailed allegations about off-label marketing do not establish that a false claim was submitted.

NNI argues that Siegel's five new allegations about her own observations and experiences as an employee fail to supply the missing link between the alleged scheme and the resulting submittal of a false claim because they are "wholly unrelated" to any interactions with any hemophilia patient or with any provider who is alleged to have prescribed NovoSeven. Dkt. 276 at 12.

First, Siegel's new pleading includes a detailed description of the binders and medical articles containing "off label marketing messages" the company's Medical Science Liaisons brought to Thomas Jefferson University's Hemophilia and Thrombosis Center while she was its director. Dkt. 270 at 50. NNI argues that Siegel does not allege that these efforts caused any physician to prescribe NovoSeven for any use, to any patient, or that any claim for any prescription was submitted to Medicare. Dkt. 276 at 12–13.

Second, Siegel alleges that, while she was at Thomas Jefferson, NNI sales representative Linda Fenlin asked her to "find a use of NovoSeven for one of [Siegel's] patients" so that a case report could be "ghost written" (and published). Dkt. 270 at 50. NNI argues that Siegel does not allege, as she must, that as a result, she prescribed NovoSeven for off-label use for any patient, or that, as a result of that, any claim for payment was submitted to Medicare.

Third, Siegel alleges that Fenlin routinely asked her about her specific treatment orders for patients, by name, demonstrating that she had access to patients' medical records. She alleges that Fenlin repeatedly asked her whether a specific patient would be given NovoSeven, at what dose, and if not, why not. Siegel alleges that she ultimately banned Fenlin from the Thomas Jefferson HTC. Dkt. 270 at 68.

NNI argues that these allegations are not reliable indicia of a false claim because they do not allege that Siegel actually prescribed NovoSeven to any patient for off-label use, much less one for whom a claim was submitted to Medicare. It also points out that

Siegel does not allege that she was even *asked* to prescribe any patient NovoSeven for an off-label use. Dkt. 276 at 13.

Fourth, Siegel alleges that while she worked at NNI, its sales employees had knowledge of specific patients in clinical trials and their "treatment patterns," and that an NNI vice president "endorsed access" to the patient list so that sales team members could "recruit them more effectively." Dkt. 270 at 68. NNI argues that Siegel does not allege, as she must, that "anyone went on to bill Medicare for NovoSeven for any such patient." It argues that Siegel does not allege any contact between its marketing department and any patient, or that the department promoted off-label use of NovoSeven to those patients, or that recruiting patients for a clinical trial is somehow "problematic." Dkt. 276 at 13.

Finally, Siegel alleges that NNI's national and international meetings are not only venues to "launder money (i.e., kickbacks)" but are also venues for "promoting off-label uses of NovoSeven." Dkt. 270 at 51. She alleges she attended a meeting in New York where paid KOL Dr. Amy Shapiro of the Indiana HTC discussed off-label use of NovoSeven, particularly the use of a single high dose rather than the FDA-approved lower dose every two hours. *Id*. Siegel also alleges that while she was employed at Robert Wood Johnson, she was paid $5,000 to attend a similar meeting in Denmark.

NNI argues that these allegations are insufficient because they fail to allege that any provider prescribed NovoSeven because of the presentation, at all, much less that they prescribed off-label use for any patient or that any claim was submitted to Medicare. It argues that Siegel has failed to allege that NNI paid Shapiro to discuss a specific use of

NovoSeven, that her presentation was promotional, or that her statements were false or misleading. And it argues that Siegel's allegations fail to allege that the Denmark meeting led to her or anyone else prescribing NovoSeven to any U.S. patient, or that any prescription led to the submittal of any claim to Medicare. It also argues that she does not allege that any speaker there was paid to attend or that any statements they made were false or misleading. Dkt. 276 at 14.

NNI argues that individually, together, or in conjunction with her other allegations, Siegel's new pleading "utterly fails" to establish any link between the underlying off-label or kickback schemes and any false claims. It argues that Siegel's new facts do not support a "strong inference" that, as a result of any of Siegel's experiences, any claims were submitted to Medicare, much less false claims. *Id*. 14–15 (citing *United States v. McKesson Corp.*, No. 19-cv-02233-DMR, 2021 WL 583506, at *5 (N.D. Cal. Feb. 16, 2021) (citation omitted), *aff'd*, *McElligott v. McKesson Corp.*, No. 21-15477, 2022 WL 728903 (9th Cir. Mar. 10, 2022) ("FCA liability attaches not to 'underlying fraudulent activity' . . . but to claims for payment[.]"))

Siegel responds that the Ninth Circuit has rejected the notion that Rule 9(b) requires her to plead an actual false claim:

> In our view, ***use of representative examples is simply one means of meeting the pleading obligation***. We join the Fifth Circuit in concluding, in accord with general pleading requirements under Rule 9(b), that ***it is sufficient to allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.***"

Dkt. 281 at 13 (citing *Ebeid*, 616 F.3d at 998–99) (other citations omitted) (emphasis Siegel's). The Court agrees that this is the standard against which Siegel's allegations must be measured.

Siegel argues most persuasively that NNI would not have continued to engage in an off-label marketing and kickback scheme of the scope she alleges in detail unless that scheme succeeded in increasing off-label uses, supporting the obvious inference that it resulted in the submittal of false claims. She argues that NNI asks the Court to "believe that the national scheme that it painstakingly developed at great cost and implemented across the country somehow impacted prescribing behavior only within the geographic boundaries of Washington State." Dkt. 281 at 8. She argues that such an argument "strains credulity. It is implausible that a fraudulent scheme of the scope alleged by [relator] would be entirely feckless." *Id*. (quoting *U.S. ex rel. Brown v. Celgene Corp*., No. CV 10–3165–GHK (SSx), 2014 WL 3605896 at *8 (C.D. Cal. 2014)). *Brown* explained:

> It would stretch the imagination to infer the inverse. To conclude that Brown's allegations do not reasonably suggest that false claims were actually submitted would require far more strained leaps of logic. We would have to believe that: (i) while Celgene went to the trouble of systematically implementing a multi-pronged fraudulent scheme to create an off-label market for Thalomid and Revlimid, (ii) these alleged fraudulent practices did not sway physicians to write prescriptions for off-label uses; but (iii) Celgene nevertheless maintained its ineffectual fraudulent scheme for years and years.

2014 WL 3605896, at *10. Siegel argues that her new allegations about her interactions with NNI's marketing representatives and her participation in NNI-sponsored events support a similarly obvious conclusion: NNI's off-label marketing and kickback scheme

was successful, or it would not have continued. She argues that her new allegations are reliable indicia supporting a strong inference that actual false claims were submitted. Dkt. 281 at 20.

NNI replies that Siegel does not articulate a clear definition of "reliable indicia" but that her new allegations fail to meet the standard Judge Wyrick correctly explained. It argues that Siegel is obligated to allege a direct link between the alleged schemes using particularized facts supporting a strong inference that the schemes were connected to false claims. Dkt. 293 at 4. It argues that Judge Wyrick already concluded that Siegel's "discussion of marketing events in several states, unlike the representative Patient A in the State of Washington, does not link any off-label promotion to alleged false claims in those states." *Id*. (citing Dkt. 174 at 22). It argues that Siegel is required, but has failed, to provide facts supporting a strong inference that the scheme she describes was linked to the submission of false claims. *Id*. (citing *U.S. ex rel. Solis v. Millennium Pharms., Inc.*, 885 F.3d 623, 629 (9th Cir. 2018) (dismissing case because relator failed to meet burden to allege details linking the alleged scheme to any claim submitted to a federal healthcare program).

NNI contends that Siegel's new allegations merely supplement her already-sufficient allegations about the existence of a scheme. It argues that she has still failed to supply the missing link between that scheme and the submittal of any *false claims* for reimbursement—a "different issue." Dkt. 293 at 6 (emphasis in original). It argues that *Brown* proves its point, because unlike Siegel, the relator there had pled specific facts supporting the required strong inference. *Id*.

Specifically, relator Brown alleged five specific facts that do not have analogs in Siegel's new pleading: (1) "[B]y Celgene's own estimates 'Medicare and Medicaid paid for the majority of . . . prescriptions'" at issue." *Brown*, 2014 WL 3605896, at *9; (2) estimates from "industry analysts" indicat[ed] that "almost all" of the drug's sales were "for off-label uses." *Id*.; (3) the "marketing scheme specifically targeted government payors." *Id*.; (4) "Sales representatives urged physicians to enroll their patients in Medicare." *Id*.; and (5) patients were specifically marketed to "'just prior' to their enrollment in government health plans." *Id.* Brown alleged that as the direct result of this scheme, false claims were submitted to Medicare. *Id*.

NNI argues that in contrast, Siegel's pleading suggests that most severe hemophilia patients are *not* covered by Medicare or Medicaid, and that, as of 2012, only 15% of NovoSeven's revenue stream was for off-label uses. Dkt. 293 at 7 (citing Dkt. 270 at 76 and 33, respectively). It argues that Siegel does not allege that NNI marketed specifically to government beneficiaries or urged patients to enroll in Medicare or Medicaid. *Id*. It argues that Siegel has failed to sufficiently plead the required "link."

In the Court's view, this is the crux of the case. There is a certain appeal to the contention that NNI would not have engaged in a scheme if it was not successful, but none of the authority cited by the parties suggests that a detailed scheme alone can supply by implication the required link that false claims must have been submitted. The authority uniformly requires reliable indicia supporting a strong inference that false claims were submitted.

Siegel's own allegations about Patient A demonstrate the distinction. Unlike her new allegations discussed above, Siegel pled specific facts about NNI's contact with, and payment to that patient, leading to off-label prescriptions that were submitted for payment. Dkt. 270 at 37, 41. None of her new allegations contain similar details about any other patient.

The Court agrees that Siegel's new allegations about her personal experiences do not fill in the "gaps" in her allegations, properly identified in Judge Wyrick's Order, Dkt. 174.

2. Siegel's aggregate Medicare claim counts do not establish that a false claim was submitted.

Siegel's second set of new allegations relate to aggregate Medicare "claim counts" that she recently obtained from the Centers for Medicare and Medicaid Service (CMS), which administers Medicare. Dkt. 270 at 76. She alleges that Medicare paid more than a billion dollars (about $100 million per year) for NovoSeven for about 200 patients between 2008 and 2017.

NNI argues that these naked claim counts are not sufficiently particularized to tie any scheme to any claim, much less a false claim. Siegel does not identify any patient who received NovoSeven, what they were treated for, whether they were treated with on- or off-label uses, and whether and to what extent they were actually reimbursed by Medicare. Dkt. 276 at 15 (citing *U.S. ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 58 (1st Cir. 2017), *superseded on other grounds as stated in Gonpo v. Sonam's Stonewalls & Art, LLC*, 41 F.4th 1, 9–10 (1st Cir. 2022)) (aggregate expenditure data was insufficiently

particular because it did not identify specific entities who submitted claims, much less the times, amounts, and circumstances of any claims).

NNI relies on cases dismissing similarly unconnected FCA claims where the relator failed to articulate the details of the allegedly false claims. Dkt. 276 at 16 (citing, among others, *U.S. ex rel. Karp v. Ahaddian*, 2018 WL 6333670, at *3 (C.D. Cal. Aug. 3, 2018)) (dismissing amended complaint because the new allegations established "only that [d]efendants received significant payments from Medicare during the 2012–15 period, not that the payments were the product of false claims"). It argues that despite experience, her high-level access to NNI's documents, and years to hone her allegations, Siegel has still failed to allege the requisite link between the alleged fraudulent scheme and Medicare claims for payment. Dkt. 276 at 16 (citing *United States v. Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213, 1222 (W.D. Wash. 2011) ("Plaintiffs, as self-described 'high level insiders,' should be able to provide specifics to support their claims.").

Siegel's response explains that the Medicare claims counts must be viewed in conjunction with her other allegations, and that they are at least circumstantial evidence plainly supporting the inference that additional false claims were filed and paid by Medicare. Dkt. 281 at 20. She contends that all her allegations are meant to provide further *national* evidence to demonstrate that the marketing ploys NNI used with Patient A were not unique to that patient, his physician, or the State of Washington. *Id*. (emphasis in original). Citing *Brown*, she asserts that her allegations of a systematic nationwide off-label and kickback scheme and extensive Medicare and Medicaid

reimbursement meet Rule 9(b)'s requirements, even though she has not provided the details of any representative false claims caused by NNI's misconduct. *Id*. at 21 (citing *Brown* at *9–10).

NNI replies that it has never disputed that Medicare reimburses for NovoSeven; the dispute is whether Siegel has sufficiently pled facts linking off-label promotion or kickbacks to a Medicare claim outside Washington, giving rise to a strong inference that the claim was false. Dkt. 293 at 5. It argues that the claim counts do not provide the required connection between the alleged scheme and any false claims outside Washington.

The Court agrees with NNI that raw claims data does little to establish the required link between its alleged misconduct and the submission of false claims. As discussed above, these allegations are not nearly as detailed as her allegations about Patient A, and they are not nearly as specific as were the relator's allegations in *Brown*. They do not themselves amount to reliable indicia supporting a strong inference that a false claim was submitted.

3. Seigel's revised allegations about Patient C in Delaware do not establish that that an FCA false claim was submitted.

Siegel's third consolidated complaint adds allegations about the number and amount of claims that were submitted to Delaware's (partly federally funded) Medicaid program on behalf of Patient C. It does so to support both her FCA claims and her Delaware state law claim.

Siegel contends that the data shows that 267 NovoSeven claims were submitted for only Patient C between 2008 and 2023. She asserts the claims were submitted regularly, including on successive days, indicating that Patient C was taking the drug "in dangerous quantities indicating use of off-label high dose regimens and/or for prophylaxis." Siegel alleges that Delaware Medicare paid $63,058,066.02 for NovoSeven for Patient C since 2008, and of that, specialty pharmacy Accredo submitted $62,330,897.91 in claims for NovoSeven. Dkt. 270 at 80.

Siegel contends that NNI paid kickbacks to Accredo through a contract that provided a 21% discount for NovoSeven, conditioned on Accredo signing up patients for NNI patient assistance programs like SevenSECURE, which in turn provided free benefits to patients for using NovoSeven. *Id*. at 82.

The Court considers these allegations as support for both Siegel's asserted national FCA claims, counts 1 and 2, and her state law Delaware False Claims Act claim, count 7.[4]

NNI argues that Siegel's effort to replicate her claims about Washington's Patient A with respect to Patient C fails. Unlike Siegel's detailed allegations tying NNI's scheme to Patient A's prescriptions, Siegel's Patient C allegations are only that: (1) Patient C had

[4] Both parties discuss Siegel's new Delaware allegations in connection with both her FCA claims (counts 1 and 2) and her Delaware state law claim (count 7). The Court will address the parties' arguments about the Anti-Kickback Statute (AKS) in its discussion of count 7, below. NNI's Reply clarifies that, as to the FCA claims, it advanced its AKS arguments in the alternative, and that the focus of its motion to dismiss is the lack of reliable indicia supporting a strong inference that false claims were made, discussed here. *See* Dkt. 293 at 4 n.3. The Court need not address this alternate basis to resolve the motion on Siegel's FCA claims.

a NovoSeven prescription that was filled at Accredo, and (2) Patient C used about $63,000,000 worth of NovoSeven, some use of which may have been off label. It contends that Siegel has failed to provide any specific details about the kickback scheme or how Accredo—which does not write, but only *fills* prescriptions—influenced the use of NovoSeven. It argues that allegations of a generalized scheme that does not provide details linking the defendant to the scheme does not satisfy Rule 9(b). Dkt. 276 at 17 (citing *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1182 (9th Cir. 2016)).

NNI argues Siegel fails to plead the requisite link between the alleged kickbacks to Accredo and any claims for payment to Delaware Medicaid. Instead, she asks the Court to find that an attenuated and multi-step chain amounts to reliable indicia supporting a strong interference that false claims were submitted. Dkt. 276 at 17. That chain includes the following: NNI's discount caused Accredo to push patients to sign up for SevenSECURE, which caused those patient to request NovoSeven from their prescribing physicians, which caused their physicians to prescribe NovoSeven, which then caused claims for NovoSeven to be submitted to Delaware Medicaid. *Id*. at 18.

NNI argues that such multi-link causation chains are not sufficient as a matter of law. *Id.* (citing *U.S. ex rel. Osinek v. Kaiser Permanente*, 2023 WL 4054914, at *14–15 (N.D. Cal. June 15, 2023)) (multi-step chain of causation involving multiple intervening actors insufficient because "downstream ripples" "are too attenuated and travel too far beyond the alleged misconduct" to support liability). NNI argues that Siegel's allegations are insufficient under Rules 9(b) and 12(b)(6).

Siegel responds that she has pled a fraudulent off-label marketing and publication scheme, and that Patient C's "extraordinary quantities" of NovoSeven, provided by Accredo, were "a product of" that scheme. She argues that the quantity and the discount together support the required inference that false claims were submitted. Dkt. 281 at 22.

Delaware has declined to intervene in the case, but it did file a "Statement of Interest" in opposition to NNI's motion. Dkt. 282. It explains that its decision not to intervene was based partly on the fact Siegel and Washington are pursuing the claims, and it need not expend additional resources joining the litigation. It argues that Siegel's new pleading resolves Judge Wyrick's concern that she had not adequately pled that false claims were submitted to Delaware Medicaid:

> Specifically, the [third consolidated complaint] now alleges that 267 claims for NovoSeven® were submitted on behalf of one patient, Patient C, to [Delaware's] Medicaid system for a total of $63,058.066.02. 229 of those claims, worth $62,330,897.91, were submitted by a specialty pharmacy named Accredo.

Id. at 7. It repeats Siegel's allegation that Accredo's discount was contingent on not only volume but on Accredo agreement to sign patients up for NNIs patient support programs (including SevenSECURE), which were designed to provide remuneration to patients. It also argues that NNI's discount required Accredo to assist patients in securing reimbursement for submitted NovoSeven claims. It contends that Siegel has plausibly alleged that false claims were submitted to, and paid by, Delaware Medicaid. It urges the Court to deny NNI's motion. *Id*. at 7 and 12.

NNI replies that the "linchpin" of Siegel's argument (and Delaware's) is the misguided allegation that its pricing contract with Accredo required Accredo to "sign up"

patients for SevenSECURE. But, it argues, that contract is incorporated into Siegel's third consolidated complaint and its "plain language" demonstrates that Accredo was instead required only to provide *information* about SevenSECURE. In other words, it claims, Accredo's discount was contingent on educating patients, not signing them up for SevenSECURE. Dkt. 293 at 8–9 (citing Dkt. 276-1 at 15). NNI also again points out that Siegel has failed to allege that Patient C (or any other Delaware patient) ever heard any off-label promotion or received remuneration from NNI. It points out that she does not even allege that Patient C in fact "signed up" for SevenSECURE. *Id*. at 9.

The Court again agrees with NNI. Siegel has not plausibly articulated any link between NNI's contract with Accredo and any false claim submitted to Delaware Medicaid. She does not explain how specialty pharmacy Accredo could influence its patients' drug choice, and the conclusory allegation that Accredo's contractual discount was contingent on signing patients up for SevenSECURE is belied by that contract. The number and amount of claims in Delaware are not reliable indicia supporting a strong inference that the claims submitted were false.

4. Seigel's alleged "schemes" in Washington, Delaware, and Indiana are distinct.

Siegel emphasizes throughout her third consolidated complaint and her response to NNI's motion that she has identified and alleged false claims submitted on behalf of eight specific patients—Patient A in Washington, Patient C in Delaware, and six Indiana HTC patients. *See* Dkt. 281 at 19. She clarifies that her Indiana allegations are based on Dr. Shapiro's role as a paid KOL, her publication of articles that were "little more than off-

label marketing messages," and her allegation that the amount of claims originating at the Indiana HTC—about $4 million per patient per year, far more than the $670,000 per year that she alleges an average on-label patient would use—and argues that these facts also support her claim that some of all of the Indiana HTC patients were treated off-label, as the result of kickbacks or off-label promotion. She contends that these facts, coupled with her other allegations, are reliable indicia supporting a strong inference that false claims were submitted, bolstering her national FCA claims. Dkt. 281 at 19–20.

NNI responds that in addition to being individually and collectively insufficient, Siegel's Washington, Delaware, and Indiana allegations are so different that they cannot support a national FCA scheme in any event. It correctly points out that disparate "representative examples" cannot collectively link a "scheme of systemic fraud" to "systemic false claims" where the representative examples are not consistent with the purported scheme. Dkt. 293 at 12 (citing *United States ex rel. Perry v. Hooker Creek Asphalt & Paving, LLC*, 565 F. App'x 669, 670 (9th Cir. 2014)).

Siegel's fraud theory about Delaware's Patient C is that NNI paid specialty pharmacy Accredo a kickback (in the form of a contingent discount) for steering patients to NovoSeven and SevenSECURE; she does not assert that NNI paid kickbacks to KOLs or NovoSeven prescribers, or to patients. Siegel does not allege that Accredo had any connection to NNI outside Delaware.

Her claims about the six Indiana HTC patients rely on her allegation that KOL Dr. Shapiro assisted NNI in promoting off-label marketing messages, and that the Indiana HTC submitted more claims than she contends would have been submitted for purely on-

label use. Siegel does not allege that Shapiro treated or even spoke to any of these patients.

In sharp contrast, Siegel alleges that NNI visited Patient A's medical facility in Washington to promote off-label uses of NovoSeven, that Patient A actually used NovoSeven off-label for prophylaxis, that NNI directly paid Patient A kickbacks to so use NovoSeven, and that as a result, Washington paid $53,042,060.19 over four years for Patient A's off-label NovoSeven use.

Siegel's new Delaware and Indiana allegations are not only far less specific than are her claims about Patient A, but they also describe a distinctly different sort of fraudulent scheme. The Court agrees that this is an additional reason that Siegel's allegations in Washington, Delaware, and Indiana do not support a national FCA claim; the alleged schemes are different, and localized. Siegel has not alleged a systemic scheme linked to "systemic" false claims. Her allegations about Delaware and Indiana are not additional representative examples of a national scheme, and they are not reliable indicia supporting a strong inference that false claims were submitted on a national scale. They are insufficient to support a national FCA claim.

NNI's motion to dismiss Siegel's re-pled national FCA claims, counts 1 and 2, is **GRANTED**. Because Siegel has already amended her complaint three times, the dismissal is with prejudice and without leave to amend.

B. Siegel's re-pled Delaware False Claims Act claim based on violations of the Anti-Kickback Statute (count 7).

The Court addressed above Siegel's new allegations about Patient C in Delaware, in connection with Siegel's claim that those allegations support a national FCA claim. Siegel also seeks to use those allegations to support and resurrect her state law Delaware False Claims Act claim, count 7. She alleges that NNI "knowingly presented or caused to be presented to the Delaware Medicaid program false claims[.]" Dkt. 270 at 93. As discussed above, this claim is based on Siegel's allegation that NNI paid Accredo kickbacks. Siegel alleges that NNI's contractual discount to Accredo violated the federal anti-kickback statute (AKS), 42 U.S.C. § 1320a-7(b)(2)(B).

NNI argues that Siegel has not pled facts sufficient to support an AKS violation in support of her Delaware claim. Dkt. 276 at 19. NNI correctly asserts that, to plead a plausible AKS claim, a plaintiff is required to allege facts supporting the conclusion that (1) knowingly and willfully, (2) offered or paid remuneration, (3) to induce the purchase or ordering of products or items for which payment may be made under a Federal healthcare program. *See* 42 U.S.C. § 1320a-7b(b)(2)(B). The plaintiff must allege that false claims "result[ed] from" the AKS violations. 42 U.S.C. § 1320a-7b(g). *See* Dkt. 276 at 9.

NNI argues that a "kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient." *Id*. (citing *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 100 (3d Cir. 2018)).

NNI argues that to plausibly plead an AKS violation based on a discount, the plaintiff must allege that the discount was "above market value" to amount to the remuneration element of an alleged AKS violation. Dkt. 276 at 19 (citing *Ctr. for Diagnostic Imaging,* 787 F. Supp. 2d at 1223). It argues that Seigel has not alleged that its 21% discount to Accredo was above market value or commercially unreasonable; indeed, it asserts, the industry standard is 22%–40% below average wholesale price (AWP). *Id*.

NNI also argues that Siegel must allege more than "mere encouragement;" she must allege that NNI had "an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business." *Id*. (citing *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995)). It contends that in the Ninth Circuit, a common business arrangement that the parties intended to be lawful, and believed to be lawful, is not enough to establish the inducement element of an AKS claim. *Id*. at 20 (citing *Hanlester*, 51 F.3d at 1399). NNI argues that Siegel's complaint concedes that discounts to specialty pharmacies are routine, and that NNI's discount to Accredo was actually less than the industry average. It emphasizes that its contract with Accredo expressly included a "compliance with laws" section, requiring both to comply with the AKS, undermining her claim that any violation was willful. *Id*.

Finally, NNI contends that by relying on the contractual discount, Siegel's new pleading "implicates" the AKS discount "safe harbor," 42 C.F.R. § 1001.952(h)(5) and 42 U.S.C. § 1320a-7b(b)(3)(A)). It contends that in this Circuit, when an alleged kickback scheme implicates an AKS safe harbor,

> plaintiffs can only plead scienter by alleging that either: (1) that the defendant "knew, or acted with reckless disregard for the fact that [the remuneration] did not fall within [the relevant] Safe Harbor Provision"; or (2) that, even if the defendant "believed that its [remuneration] fell under the Safe Harbor Provision" it was really only provided in furtherance of the alleged improper purpose.

Dkt. 276 at 21 (citing *United States v. Corinthian Colleges*, 655 F.3d 984, 997 (9th Cir. 2011)). It argues that Siegel has not alleged either form of scienter and, as a result, her Delaware state law claim based on an AKS violation fails as a matter of law. *Id*.

Sigel responds that the safe harbor is an affirmative defense that cannot support a Rule 12(b)(6) motion, and she need not refute it. Dkt. 281 at 22 (citing *United States v. George*, 171 F. Supp. 3d 810, 818 (N.D. Ill. 2016) ("Safe-harbor provisions are an affirmative defense that must be proven by the [d]efendant."). She also contends that her alleged discount off *AWP* was a clerical error; she contends the discount was off the lower wholesale acquisition cost (WAC). *Id*. at 23 (citing Dkt. 276-1 at 1). She also argues that NNI must satisfy all elements of the safe harbor to take advantage of it. She argues that because her pleading "itself does not unambiguously establish all of the elements required for the safe harbor to apply, dismissal is not appropriate on that basis." *Id*. at 25 (citing *United States ex rel. Derrick v. Roche Diagnostics Corp.*, 318 F. Supp. 3d 1106, 1114 (N.D. Ill. 2018)).

Siegel also argues that she has sufficiently alleged that NNI's violation of the AKS was willful. She argues she does not need to allege or prove that NNI knew it was violating the law; it is enough to allege that it willfully committed an act that violated the AKS. *Id*. at 26 (citing *United States ex rel. Hueseman v. Pro. Compounding Centers of*

Am., Inc., No. SA-14-CV-00212-XR, 2023 WL 2669879, at *10 n.4 (W.D. Tex. Mar. 27, 2023)). Sigel argues that in this Circuit, it is sufficient to allege that "one purpose" of the contractual arrangement was illegal, even if a legitimate business purpose is also present. *Id*. (citing *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989)). She again contends that "one purpose" of the contract was to induce Accredo to "recommend NovoSeven to patients, to sign them up for SevenSECURE, and to provide aid in getting claims for NovoSeven reimbursed." *Id*. at 27. She contends she sufficiently alleges that NNI acted with the required scienter, and that factual questions about the safe harbor's application cannot be resolved at the pleading stage. *Id*.

NNI replies that in the Ninth Circuit, when a complaint implicates the safe harbor, the plaintiff must allege facts showing the safe harbor does not apply. Dkt. 293 at 10 (citing *Corinthian* at 997, and *U.S. ex rel. Chao v. Medtronic PLC*, 2021 WL 4816647, at *6 (C.D. Cal. Apr. 12, 2021)) ("Due to these [AKS] safe harbors, Relator must sufficiently allege facts showing payments fall outside protected categories in order to state a plausible claim for relief."). Siegel's contrary out-of-circuit authority is not persuasive on this point.

NNI also points out that Siegel's allegations are inconsistent: she incorporates and expressly relies on the contract, which reflects that NNI and Accredo believed they were complying with the AKS. *See* Dkt. 276-1 at 4. At the same time, she alleges that "one purpose" of the contract was to provide illegal inducements. NNI argues, persuasively, that where a complaint's allegations are refuted by the attached document, the document controls. Dkt. 293 at 10 (citing *Harris v. City of Seattle*, 2003 WL 1045718, at *4 (W.D.

Wash. Mar. 3, 2003)) ("[W]hen allegations of the complaint are clearly refuted by an attached document, the Court need not accept conflicting allegations of the complaint as true and may dismiss the claim.").

The Court agrees on this point as well. Siegel's conclusory allegations about the import and purpose of the NNI/Accredo contract are discussed above. The contract facially does not make Accredo's discount contingent on it "signing up" patients for SevenSECURE. Dkt. 276-1 at 15. Seigel's complaint implicates the contract, and the contract does not say what she claims it says. She has not sufficiently alleged that the safe harbor does not apply. She has not sufficiently pled that the discount was a remuneration, that the contract was an inducement, or that NNI acted willfully. *See United States v. Valley Campus Pharmacy, Inc.*, 2021 WL 4816648, at *13 (C.D. Cal. June 23, 2021) (AKS claim dismissed where relator did not plead the defendant knew the conduct was unlawful, even if it pled the defendant knowingly acted.).

Siegel has not sufficiently pled[5] an AKS-based Delaware False Claims Act claim. NNI's motion to dismiss this claim is **GRANTED**. Because Siegel has already amended her complaint three times, the dismissal is with prejudice and without leave to amend.

The pending motions to compel, Dkts. 285, 316, will be addressed in a separate Order.

IT IS SO ORDERED.

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[5] Because the claim is dismissed, the Court need not address whether the claim would relate back to the date of Siegel's initial filing.

Dated this 30th day of July, 2024.

BENJAMIN H. SETTLE
United States District Judge